James R. Condo (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

This Document Relates to:

Lisa Hyde, et al. v. C. R. Bard, Inc., et al.
CV-16-00893-PHX-DGC

No. 2:15-MD-02641-DGC

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 1 TO EXCLUDE OR LIMIT FDA EVIDENCE THAT IS BEYOND THE SCOPE OF THE COURT'S ORDER

(Assigned to the Honorable David G. Campbell)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Plaintiffs move to exclude relevant FDA evidence and testimony, including certain post-market surveillance evidence and a December 1996 FDA down-classification memorandum (the "Price Memo"), that they contend is beyond the scope of the Court's Order (Doc. 9881). This Court should deny Plaintiffs' motion for four reasons.

First, Bard's post-market surveillance efforts and related communications with FDA, are precisely the type of lack of FDA action evidence that this Court found relevant to negligent design and punitive damages under Georgia law, because it is probative of the reasonableness of Bard's design decisions and lack of disregard for patient safety. *See* Docs. 10323 at 2-3; 11011 at 4-5 ("To counter [Plaintiffs' many FDA-related arguments], Defendants should be permitted to present evidence regarding their communications with the FDA and its lack of enforcement action with respect to their filters."); Ex. A, Final Pretrial Conf. Tr. at 33:3 to 43:7, *Booker v. C. R. Bard, Inc., et al.* (D. Ariz. Mar. 2, 2018). This evidence is equally relevant to Plaintiffs' claims for negligent design and punitive damages under Wisconsin law.[1] *See Stevens v. Stryker Corp.*, No. 12-CV-63-bbc, 2013 WL 4758948 (W.D. Wis. Sept. 4, 2013) (applying Wisconsin law) (holding that FDA regulations may inform the reasonableness of a manufacturer's design under Wisconsin negligence law); Wis. Stat. § 895.043(3) (Punitive damages warranted only where "the defendant acted maliciously . . . or in an intentional disregard of the plaintiff's rights.").

This post-market surveillance evidence is also relevant to Plaintiffs' strict liability design defect claim. After FDA's multiple clearances of the Recovery® and G2® filters, Bard and FDA repeatedly communicated about the post-market performance of the devices. (*See* Pls.' Exs. D-G, N.) This included, for example, Bard's efforts to monitor caudal migration observed with the G2 Filter. Notwithstanding FDA's awareness of the reported complications rates with the devices, FDA took no enforcement action with

[1] To the extent Plaintiffs can base their negligence per se claim on violations of the FDCA and its implementing regulations, which Bard denies, this evidence is directly probative of those claims. *See* Doc. 364 ¶ 231. For example, Trial Exhibits 5879-5881, and 5003 (Pls.' Exs. D-G, N) concerning Bard's DFMEA and Dear Colleague Letter are directly probative of Bard's alleged violations of the quality systems regulations, 21 C.F.R. § 820 *et seq.*, and any alleged violations of 21 U.S.C. § 321, and 21 C.F.R. §§ 803, 807.

respect to the Recovery or G2 filters. This evidence is relevant to Bard's decision to adopt the design of the G2®X (G2 with snarable tip) and Eclipse® (electropolished G2X) filters over other alleged "reasonable alternative design[s]," whether Bard's "omission of the alternative design renders [the G2X or Eclipse] not reasonably safe," Wis. Stat. § 895.047(1)(a), and whether Bard's decision to continue to sell the devices was reasonable.

Similarly, the Price Memo (Pls.' Ex. H) is probative of Plaintiffs' claims, as it evidences FDA's and the medical community's acknowledgment of known risks (including those at issue in this case) and acceptable complication rates for IVC filters as reported in the literature. This is highly relevant to establish that the alleged "damage [here] was caused by an inherent characteristic of the product" that was well known "to the community that uses [IVC filters]." Wis. Stat. § 895.047(3)(d). This is also relevant to Bard's decision to adopt the specific design of the G2X and Eclipse over other alleged alternative designs because Bard's G2 EVEREST clinical rates fell within this accepted range. *See* Wis. Stat. § 895.047(1)(a).[2] The Price Memo is further relevant to other issues because: (1) it explains why IVC filters are subject to 510(k), rather than PMA, review, rebutting Plaintiffs' arguments in opening that Bard "chose this path of clearance, not approval"[3] and otherwise criticizing Bard's pre-market testing; (2) it evidences FDA's acknowledgment of the benefits of IVC filter use, rebutting Plaintiffs' argument that IVC filters lack efficacy; and (3) it explains why FDA promulgated the IVC Filter Guidance, with which all of Bard's IVC filter 510(k) submissions complied.

Second, Plaintiffs offer no new argument for exclusion of this relevant evidence. This Court has already heard and addressed Plaintiffs' arguments that they are prejudiced because "Plaintiffs are precluded from deposing FDA officials." (Mot. at 2.) The Court

[2] *See also Restatement (Third) of Torts: Prod. Liab.* § 2, cmt. d (1998) ("Assessment of a product design [requires] comparison between an alternative design and the product design that caused the injury, undertaken from the viewpoint of a reasonable person."); *id.* at cmt. f (some factors to consider whether omission of alternative design rendered the product not reasonably safe include: "the magnitude and probability of the foreseeable risks of harm" and "the instructions and warnings accompanying the product").

[3] Ex. B, Trial Tr. Day 1, at 145:1-8, *Booker v. C. R. Bard, Inc.* (D. Ariz. Mar. 14, 2018).

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

concluded that "Plaintiffs have ample evidence to contest Defendants' assertions that they were fully transparent with the FDA." Doc. 10323 at 3; *see also* Ex. A at 41:1 to 42:2 ("Plaintiffs have been thorough in deposing every witness who claims to have communicated with the FDA, and obtaining every document that was shared with the FDA, and identifying lots of evidence that . . . was not shared with the FDA, [and have two regulatory] experts who will opine about what the FDA does and does not do."). The probative value of this evidence substantially outweighs any danger of unfair prejudice.

Third, Plaintiffs misinterpret the scope of this Court's Order (Doc. 9881), which addressed only Plaintiffs' specific request to exclude two categories of evidence: (1) FDA 510(k) clearance, and (2) lack of FDA enforcement action. *See* Docs 9881 at 1; 9529, 9824. Plaintiffs did not move to exclude, nor did the Court rule on the admissibility of, all FDA or "regulatory evidence." Moreover, the Court did not limit Bard's use of FDA evidence only to such evidence "relevant to the 510(k) clearance process." (Mot. at 2.) Additionally, Plaintiffs ignore the other half of the Court's Order and subsequent rulings denying their request to exclude evidence of lack of FDA action. *See* Docs. 9881; 10323 at 2-3; 11011 at 4-5. In short, most of the evidence Plaintiffs seek to exclude here falls squarely within the lack of FDA action category and is relevant to the issues in this case.

Fourth, Plaintiffs move to exclude any "gratuitous" testimony concerning "FDA communications unrelated to the 510(k) process." (Mot. at 3.) It is unclear to Bard what testimony Plaintiffs seek to exclude. But Bard submits that its communications with FDA are relevant to provide context for the reasonableness of Bard's actions and state of mind in designing the G2X and Eclipse over other reasonable alternative designs. *See* Doc. 11011 at 4 ("Defendants should be permitted to present evidence regarding their communications with the FDA.").[4] Nor is it possible for Bard to respond to or the Court to rule on this vague request without the context in which the testimony is offered at trial.

[4] Plaintiffs' assertion that Bard's witnesses testified "directly that its filters were *deemed* safe and effective" is inaccurate. (Mot. at 3 (emphasis added).) That Mr. Carr personally believes that retrievable filters "are safe and effective" is a far cry from testifying that they were "deemed" so by FDA. (Pls.' Ex. M.)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

For these reasons, Bard respectfully requests that the Court deny this Motion.

RESPECTFULLY SUBMITTED this 28th day of August, 2018.

s/ Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

James R. Condo (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
jcondo@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000